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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.              | CONFIRMATION NO.       |
|--|-------------|----------------------|----------------------------------|------------------------|
| 10/575,624   | 04/13/2006  | Eiko Kato            | Q78079                           | 4641                   |
| 23373 7590 04/14/2009<br>SUGHRUE MION, PLLC<br>2100 PENNSYLVANIA AVENUE, N.W.<br>SUITE 800<br>WASHINGTON, DC 20037 |             |                      | EXAMINER<br>SULLIVAN, DANIELLE D |                        |
|  |             |                      | ART UNIT<br>1616                 | PAPER NUMBER           |
|  |             |                      | MAIL DATE<br>04/14/2009          | DELIVERY MODE<br>PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/575,624

**Applicant(s)**

KATO ET AL.

**Examiner**

DANIELLE SULLIVAN

**Art Unit**

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 April 2006.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-18 is/are rejected.  
7) ☒ Claim(s) 3-18 is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO/SE/IB)  
Paper No(s)/Mail Date 4/13/2006 and 7/13/2006  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 1-18 are pending examination.

#### ***Claim Objections***

Claim 3 is objected to because of the following informalities: "myristic acic" should be spelled "myristic acid". Appropriate correction is required.

Claims 4-14 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend upon a multiple dependent claim. See MPEP § 608.01(n).

#### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 15 and 16 provides for the use of a polyhydric alcohol, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 15 and 16 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6, 7, 11-15 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Ito et al. (EP 1077066).

Ito et al. discloses an agent for preventing and treating skin diseases comprising an ascorbic acid derivative of formula (I) with a moisturizer selected from polyhydric alcohols such as propylene glycol and dipropylene glycol [0028], [0075] and [0078]. The salts of the ascorbic acid derivatives include sodium, potassium, magnesium and zinc [0056]. Example 8 discloses a cream comprising propylene glycol (6%), sodium 6-palmitoyloxy-L-ascorbic acid-2-phosphate (7%) and water.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5 and 8-10, 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ito et al. (EP 1077066).

### **Applicant's Invention**

Applicant claims an agent comprising a) a salt of higher fatty acid ester of ascorbic acid-2-phosphoric acid ester and b) a polyhydric alcohol. Claim 5 specifies the higher fatty acid residual group is 2-hexyldecanoic acid. Claims 8, 9, 16 and 18 specify the polyhydric alcohol is a dihydric alcohol of 5 or 6 carbons selected from dipropylene glycol. Claim 10 further limits the polyhydric alcohol to 0.05% to 12.

### **Determination of the scope and the content of the prior art**

#### **(MPEP 2141.01)**

The teachings of Ito et al. are addressed in above 102(b) rejection. Ito et al. teach the fatty acid residual group is preferably an alkyl group of 4 to 21 carbons atoms and that they are preferably long-chain fatty acids [0047]-[0054]. Examples 1-4 disclose dipropylene glycol with sodium L-ascorbic acid-2-phosphate or potassium L-ascorbic acid-2-phosphate.

### **Ascertainment of the difference between the prior art and the claims**

#### **(MPEP 2141.02)**

Ito et al. do not disclose an example where the fatty acid residual group of formula (I) is 2-hexyldecanoic acid or where the polyhydric alcohol is a dihydric alcohol selected from dipropylene glycol. However, Ito et al. teach fatty acid residual groups which are 4 to 21 carbon atoms long. This encompasses a 2-hexyldecanoic acid which has 16 carbon atoms. Therefore, although not explicitly taught, the residual group is encompassed by the teachings of Ito et al. Furthermore, an ascorbic acid-2-phosphate salt of a higher fatty acid ester is not disclosed with dipropylene glycol. Nevertheless,

examples 1-4 disclose dipropylene glycol with sodium L-ascorbic acid-2-phosphate or potassium L-ascorbic acid-2-phosphate.

### **Finding of prima facie obviousness**

#### **Rationale and Motivation (MPEP 2142-2143)**

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Ito et al. to utilize 2-hexyldecanoic acid as the fatty acid residual group in formula (I). One would have been motivated to include this residual group because Ito et al. teach fatty acid residual groups which are 4 to 21 carbon atoms long which encompass 2-hexyldecanoic acid which have 16 carbon atoms.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Ito et al. to utilize dipropylene glycol. One would have been motivated to include dipropylene glycol because Ito et al. teach examples where dipropylene glycol can substitute as a moisturizer in place of propylene glycol.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Schehlmann et al. (US 6,124,274).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Danielle Sullivan whose telephone number is (571) 270-3285. The examiner can normally be reached on 7:30 AM - 5:00 PM Mon-Thur EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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